EMERGENCY USE AUTHORIZATION (EUA) SUMMARY
MOUNT SINAI SARS-CoV-2 ASSAY
(The Mount Sinai Hospital, Center For Clinical Laboratories)

For *In vitro* Diagnostic Use
Rx Only
For Use by individuals 18 years of age and older when self-collected
For Use by individuals 14 years of age and older when self-collected under adult supervision
For Use by individuals 5 years of age and older when collected with adult assistance
For use under Emergency Use Authorization (EUA) only

(The Mount Sinai SARS-CoV-2 Assay will be performed at Mount Sinai COVID Laboratory, located at 281 First Avenue, 12th Floor Dazian Building, Room 1201, New York, NY 10003, which is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a and meets requirements to perform high complexity tests as per Laboratory Standard Operating Procedures that were reviewed by the FDA under this EUA.)

INTENDED USE

The Mount Sinai SARS-CoV-2 Assay is a real-time reverse transcription polymerase chain reaction (RT-PCR) test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in saliva specimens that are collected at home using the Mount Sinai SARS-CoV-2 Collection Kit by any individuals age 18 years and older (self-collected), 14 years and older (self-collected under adult supervision), or 5 years and older (collected with adult assistance), including from individuals without symptoms or other reasons to suspect COVID-19, when determined to be appropriate by a healthcare provider. Saliva specimens collected at home can be transported at ambient temperature to the laboratory for testing.

Testing is limited to Mount Sinai COVID Laboratory, located at 281 First Avenue, 12th Floor Dazian Building, Room 1201, New York, NY 10003, which is certified under Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meets requirements to perform high complexity tests.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in saliva specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information. Negative results for SARS-CoV-2 RNA from saliva should be confirmed by testing of an alternative specimen type if clinically indicated.

The Mount Sinai SARS-CoV-2 Assay is intended for use by qualified laboratory personnel specifically instructed and trained in the techniques of real-time PCR and *in vitro* diagnostic procedures. The Mount Sinai SARS-CoV-2 Assay and the Mount Sinai SARS-CoV-2 Collection Kit are only for use under the Food and Drug Administration's Emergency Use Authorization.

DEVICE DESCRIPTION AND TEST PRINCIPLE

1. Device Description

The Mount Sinai SARS-CoV-2 Assay is intended to be used with saliva specimens collected using Mount Sinai SARS-CoV-2 Collection Kit which consists of a bar-coded empty sterile specimen container, biohazard specimen bag, funnel and instructions for saliva collection.

Table 1: Kit components

Name	Description	Quantity	Material Supplier[1]	Part Number
Empty sterile collection container	Empty sterile polypropylene collection tube with screw-top cap and solid measurement markings, to self-collect saliva specimen	1	LabCon / Cell Treat Scientific products	3146-335-008
Specimen Bag	A 6" x 9" biohazard specimen bag	1	Medline	Q771
Funnel	A funnel to assist collection in younger children (<7 yrs)	1	United States Plastic Corp	78101
Instructions For Use	Step-by-step instruction for collecting saliva specimen	1	Mount Sinai COVID laboratory	N/A

2. Mount Sinai SARS-CoV-2 Assay

The Mount Sinai SARS-CoV-2 Assay is based on the FDA-authorized PerkinElmer New Coronavirus Nucleic Acid Detection Kit (EUA200055), manufactured by PerkinElmer, Inc and has been validated for use with saliva samples collected using the Mount Sinai SARS-CoV-2 Collection Kit.

[1] Mount Sinai currently procures materials for the Home Collection Kit from the suppliers listed in this table. As availability and cost of supplies may vary in the future, Mount Sinai may substitute equivalent materials manufactured by other suppliers, but in all cases, will procure materials for use in the Home Collection Kit only if the materials conform to the essential specifications described in this submission and they are manufactured in compliance with applicable law and FDA regulations and guidance for such devices.

3. Collection Device Stability:
The Mount Sinai SARS-CoV-2 Collection Kit does not use or include any reagents or other components that require stability testing. The kit uses an empty, sterile leak-proof tube (with an expiration date) for transportation of specimens.

4. Mount Sinai SARS-CoV-2 Testing Program
The Mount Sinai SARS-CoV-2 Assay will be used for screening students in schools and employees in business organizations. For school-based testing, participants (e.g., students, teachers, and staff) will be tested at the frequency determined by the Mount Sinai COVID Lab team and its logistics partner, C-19 Safety First, in consultation with the assigned local school board Onsite COVID Coordinator. The C-19/Verbosity platform will notify the selected group of participants regarding the date and time of testing for students and parents/guardians, in alignment with the protocols established by local regulatory bodies. In addition, clear signage will be produced and made visible on the day of testing, directing all participants to the proper location for sample drop-off (or saliva collection, if needed).

Testing programs for other entities will be coordinated through C-19 Safety First in collaboration with the respective parties, taking into account local, state and/or federal guidelines.

5. Mount Sinai SARS-CoV-2 Collection Kit ordering distribution
To obtain a Mount Sinai SARS-CoV-2 Collection Kit, individuals (or their parents/guardians, if minors) must enroll in a screening program that is sponsored by the individual's school, employer or other entity and provide informed consent. A standing order prescription from an appropriately licensed and credentialed healthcare provider will be established for each separate screening program. Under no circumstance will a collection kit be provided to an individual without a prescription order.

Mount Sinai's partner, C-19 Safety First, will manage the distribution of the Home Collection Kits at each assigned school, business or other location. As appropriate, this will be done collaboratively with the Onsite COVID Coordinator. The Mount Sinai SARS-CoV-2 Collection Kit includes clear instructional materials on how to collect and drop-off an individual COVID sample. Kit distribution will be accompanied by an email to the individual (or parent/guardian) with instructions on how to register the kit and where to drop-off the sample within a specified time window.

6. Mount Sinai SARS-CoV-2 Collection Kit Use
Upon receiving the kit, the user (or their parent/guardian) must read the Instructions For Use carefully and thoroughly before proceeding to kit registration and sample collection. Kits must be registered on the c19dropbox.com portal. During registration, the individual will take note of the drop-off location and time.

The Mount Sinai SARS-CoV-2 Collection Kit comes with a barcoded sterile screw-cap polypropylene tube as described in **Table 1** and a funnel that must be attached to the tube prior to sample collection. The individual collects 2 ml (up to the fill mark) of saliva, discards the funnel, seals the tube and repackages it in the specimen bag, following the instructions. The sample should be dropped-off within 36 hours at a designated collection receptacle. During online kit

registration by the user, sample collection date/time is recorded automatically into the Mount Sinai laboratory information management system (LIMS). The kit registration portal also provides the information on sample drop-off time and location. Mount Sinai Collection site specialists will be available on-site to assist with specimen drop-off. Specimens will not be stored more than 4 hours at the drop-off location before being transported to the laboratory by trained medical couriers in accordance with federal, state, and local regulations.

7. Laboratory Processing (Sample accessioning)
Specimens received at the Mount Sinai laboratory for testing will undergo the laboratory's receipt quality control check prior to acceptance for testing as per the laboratory's SOP. The pre-barcoded specimens are scanned into the laboratory information system and the time of receipt is recorded. Rejection criteria include specimen leakage, missing kit barcode, inadequate specimen volume (less than 1 ml), and prolonged storage or transport time (total time > 48 hours prior to receipt). Individual users and the screening program administrators are notified of rejected specimens.

8. Result reporting
Negative and invalid test results are communicated directly to individual users via their choice of text message, email, or phone call. Positive test results are reported to individual users by telephone. All results will be reported to regulatory agencies, as required by law. Positive results will be conveyed to the individuals by trained and qualified Mount Sinai employees from the Laboratory Client Service Center using a standardized script. Subjects can also contact Mount Sinai Laboratory Client Service Center with questions about their results, whereupon agents will direct individuals to the Fact Sheet for Patients but will not offer assistance with result interpretation or explanation. Any additional questions that cannot be addressed in this manner will be referred to a Mount Sinai Health System healthcare provider. In addition to the individual test recipients, the screening program administrators are notified of all results.

REAGENTS, EQUIPMENT, AND SUPPLIES

a. Equipment
The following is the list of equipment required for the procedure

Table 2: Equipment

Equipment	Manufacturer	Model and /software version
Janus	PerkinElmer	G3, and software V5.5.48
Chemagic	PerkinElmer	360, and software V6.1.0.5
QuantStudio 5 Real-Time PCR Instrument	Life technologies	QS5, and software V1.5.1
Bio-Rad CFX 384 Well Thermal Cycler	Bio-Rad	CFX384, and software V5.2.008.0222
Sorvall Centrifuge	ThermoFisher Scientific	ST8
Mini Centrifuge	ThermoFisher Scientific	mySPIN 6

Vortex Mixers	ThermoFisher Scientific	Digital
Pipetters	ThermoFisher Scientific	Pipet-Lite XLS+
Double door lab refrigerators (+4 ºC)	ThermoFisher Scientific	TSG Series
Lab Freezer (-20 ºC)	ThermoFisher Scientific	TSX Series
Lab Freezer (-80 ºC)	ThermoFisher Scientific	TSX Series

b. Consumables/Supplies
The following is the list of supplies required for the procedure

Table 3: Supplies

Product Description	Manufacturer	Catalog
900ul Filter Tips, Conductive	PerkinElmer	6001256
175ul Conductive Tips	PerkinElmer	6000687
P50	PerkinElmer	6001302
P235 MDT Tips	PerkinElmer	6001289
25ul Conductive Filter Tips	PerkinElmer	600691
8-tip Reagent Troughs	PerkinElmer	6008104
Nunc EZFlip Conical Centrifuge Tubes, 15ml	ThermoFisher Scientific	362694
Nunc EZFlip Conical Centrifuge Tubes, 50ml	ThermoFisher Scientific	362696
Heat-Resistant Film for PCR, Polyester	VWR	89496-565
MicroAmp EnduraPlate Optical 384-Well Clear Reaction Plates	ThermoFisher Scientific	A36931
SoftFit-L Filtered Pipette Tips, 20ul	ThermoFisher Scientific	2749-HR
SoftFit-L Filtered Pipette Tips, 200ul	ThermoFisher Scientific	2769-HR
SoftFit-L Filtered Pipette Tips, 1ml	ThermoFisher Scientific	2779-HR
Fisherbrand Premium Microcentrifuge Tubes: 1.5mL	Fisher Scientific	05-408-129

c. Reagent Kits
The following is the list of reagent kits required for the procedure

Table 4: Reagents

Reagent	Manufacturer	Catalog	Storage Temperature
Chemagic Viral DNA/RNA kit	Perkin Elmer	CMG -1033-S	Room Temperature
PerkinElmer New Coronavirus Nucleic Acid Detection Kit	Perkin Elmer	2019-nCoV-PCR-AUS	-25°C to -15°C

Table 5: PerkinElmer New Coronavirus Nucleic Acid Detection Kit Components

Materials Provided	Shipping Condition	Storage Temperature
• nCoV Reagent A • nCoV Reagent B • nCoV Enzyme Mix • nCoV Internal Control • nCoV Positive Control • nCoV Negative Control	Dry Ice	-25°C to -15°C

CONTROLS

Positive and negative test controls must be included and examined prior to interpretation of the test results. The PerkinElmer New Coronavirus Nucleic Acid Detection Kit provides negative, positive, and internal controls to monitor the reliability of the entire process from sample extraction to PCR amplification. The following conditions for the controls (**Table 6**) must be met to conclude that the assay system is working as expected.

Table 6: Mount Sinai SARS-CoV-2 assay controls

Control type	Ct		
	N (FAM)	ORF1ab (ROX)	IC (HEX/VIC)
Negative	Undetermined or > 42	Undetermined or > 42	Ct ≤ 40
Positive	≤ 37	≤ 37	/

/: No requirements on the Ct values

1. Negative Control: both ORFlab and N of SARS-CoV-2 must be not detected, and the Ct value of internal (IC) control should be ≤ 40.
2. Positive Control: both ORFlab and N of SARS-CoV-2 must be detected, and their Ct values must fall within the ranges described in the above tables, the Ct value of internal control does not have to be ≤ 40 for positive control.

The assay includes an RNA internal control (IC, bacteriophage MS2) to monitor specimen processing, extraction, amplification, and detection.

b. Examination and Interpretation of Patient Specimen result: The following chart (**Table 7**) describes the algorithm for interpreting the results obtained with the Mount-Sinai SARS-COV-2 Assay from patient specimens.

Table 7: Result Interpretation

Ct		Result interpretation
IC (VIC/HEX)	**N (FAM), ORFlab (ROX)**	
≤40	Both targets Undetermined or >42	SARS-CoV-2 not detected
/	Both targets ≤42	SARS-CoV-2 detected
/	One of the targets ≤42	SARS-CoV-2 detected
>40 or Undetermined	Both targets Undetermined or >42	Invalid result, specimen needs to be re-tested from re-extraction or re-collected from patient for test.

/: No requirements on the Ct values

1. If SARS-CoV-2 RNA is not detected, the Ct value of the internal control must be ≤ 40 to report a negative result, otherwise the result of that specimen is "invalid."
2. If SARS-CoV-2 RNA detected, the Ct value of the internal control is not considered.

PERFORMANCE EVALUATION

1) <u>Limit of Detection (LoD) for Saliva specimen- Analytical Sensitivity:</u>

The LoD Study determined the lowest concentration of SARS-CoV-2 RNA that can be detected by the Mount Sinai SARS-CoV-2 Assay ≥95% of the time. Quantified SARS-CoV-2 in clinical matrix was used to spike SARS-CoV-2 negative pooled saliva. Twenty replicates of five spiked serial dilutions and ten replicates of negative matrix were tested using a QuantStudio 5 Real-time PCR instrument. Results were interpreted according to the algorithm described in **Tables 6** and **7**, above. All reactions were valid as the MS2 phage internal control was detected in all replicates, and all negative control replicates were negative for SARS-CoV-2.

The limit of detection (LoD) was determined to be 100 copies/mL (**Table 8**).

Table 8: LoD determination: Mount Sinai SARS-CoV-2 Assay

Conc. (copies/mL)	Positive/Tested
200	20/20 (100%)
100	20/20 (100%)
50	15/20 (75%)
25	8/20 (40%)
12.5	7/20 (35%)

6.25	7/20 (35%)
3.125	1/20 (5%)
0 (Negative Control)	0/10 (0%)

2) **PCR Instrument Bridging Study**
To support the use of BioRad CFX 384-well thermal cycler as an alternative PCR instrument to the QuantStudio 5, Mount Sinai conducted a bridging study by testing 20 assay replicates on the BioRad CFX at the claimed LoD concentration determined using the QuantStudio 5 (i.e., 100 copies/mL). All 20 replicates produced positive results with mean Ct values for the SARS-CoV-2 targets and internal control (IC) that were within ± 1 of those obtained with the QuantStudio 5 instrument.

Additional testing performed on both PCR instruments with 30 positive and 30 negative clinical saliva samples showed 100% concordance. Among the positive samples in this study, 30% were considered low positives based on analysis of the associated Ct values. Therefore, use of both the QuantStudio 5 Real-Time PCR instrument and the BioRad CFX 384-well thermal cycler is acceptable for performing the Mount Sinai SARS-CoV-2 Assay.

3) <u>Inclusivity and Cross-reactivity</u>
The Mount Sinai SARS-CoV-2 Assay uses primers and probes from the FDA-authorized PerkinElmer New Coronavirus Detection Kit. Mount Sinai obtained a Right of Reference from PerkinElmer to leverage both inclusivity and cross-reactivity data from PerkinElmer's EUA (EUA200055). According to the Instructions For Use for the PerkinElmer assay (v9.0), a 3-nucleotide base substitution (GGG -> AAC) at the 5' end of the forward primer for the N gene target has recently been identified. A risk-based analysis conducted by PerkinElmer determined that the likelihood of the identified mutation impacting the sensitivity of N gene target is low. Furthermore, the algorithm for the Mount Sinai SARS-CoV-2 Assay requires only one of the two target genes (N or ORF1ab) to be detected to report a positive result. Therefore, the likelihood of an adverse impact on clinical performance from mutations in the region of the N gene forward primer is considered low.

4) <u>Shipping Sample Stability:</u>
Mount Sinai conducted two sample stability studies for saliva specimens that are transported using the Mount Sinai SARS-CoV-2 Collection Kit. In the first study, both high (10x LoD) and low (2x LoD) positive, and negative samples were prepared using pooled specimen matrix. The samples were cycled through both summer and winter temperature profiles in accordance with FDA's recommended stability study design for home collection kits. Both stability studies were conducted using the BioRad CFX 384-well thermal cycler. The results of this study demonstrated the stability of saliva specimens under domestic shipping conditions for up to 56 hours (**Table 9**). In addition, Mount Sinai also conducted a second study by incubating SARS-CoV-2 positive samples at different temperatures (ranging from 4 °C to 40 °C) for up to 72 hours. This study showed that the mean Ct values remained within ± 1 of those at baseline (time 0) for up to 72 hours under these conditions.

Together, these data support the stability of saliva samples collected with the Mount Sinai SARS-CoV-2 Collection Kit for up to 72 hours.

Table 9: Sample Stability

Sample group	Temperature profile	Total number of replicates tested	Percent Concordance of total number
Low Positive (2x LoD)	Summer -56 hrs [1]	20	100 (20/20)
	Winter -56 hrs [2]	20	100 (20/20)
	4 °C for 72 hrs	20	100 (20/20)
	25 °C for 72 hrs	20	100 (20/20)
	40 °C for 72 hrs	20	100 (20/20)
High Positive (10x LoD)	Summer -56 hrs [1]	10	100 (10/10)
	Winter -56 hrs [2]	10	100 (10/10)
	4 °C for 72 hrs	10	100 (10/10)
	25 °C for 72 hrs	10	100 (10/10)
	40 °C for 72 hrs	10	100 (10/10)
Negative	Summer -56 hrs [1]	10	0 (0/10)
	Winter -56 hrs [2]	10	0 (0/10)
	4 °C for 72 hrs	10	0 (0/10)
	25 °C for 72 hrs	10	0 (0/10)
	40 °C for 72 hrs	10	0 (0/10)

[1] 8 hrs at 40 °C; 4 hrs at 22 °C; 2 hrs at 40°C; 36 hrs at 30 °C; 6 hrs at 40°C
[2] 8 hrs at -10 °C; 4 hrs at 18 °C; 2 hrs at -10 °C; 36 hrs at 10 °C; 6 hrs at -10°C

5) Clinical Validation:

a. Paired specimen study: Mount Sinai conducted a validation study to evaluate saliva as a specimen type for detection of SARS-CoV-2 nucleic acid using the Mount Sinai SARS-CoV-2 Assay. The study was performed using paired saliva and nasopharyngeal (NP) swab specimens that were collected from symptomatic and asymptomatic patients. The paired NP swab

specimens were tested using an FDA-authorized comparator according to the authorized Instructions For Use, while the saliva specimens were tested using the Mount Sinai SARS-CoV-2 Assay and the QuantStudio 5 Real-time PCR instrument. A total of 60 saliva specimens were included in the study, with 60 paired NP swabs (30 positive/30 negative). Results showed that PPA and NPA were both 100% between paired saliva and NP swab specimens (**Table 10**).

Table 10: Summary of the paired specimen study

Mount Sinai SARS-CoV-2 Assay		**FDA-Authorized Comparator: Nasopharyngeal swabs**		
		Positive	**Negative**	**Total**
Saliva	**Positive**	**30**	**0**	**30**
	Negative	**0**	**30**	**30**
	Total	**30**	**30**	**60**
Positive Agreement		**100% (30/30); 95% CI* (88.7, 100.0)**		
Negative Agreement		**100% (30/30); 95% CI* (88.7, 100.0)**		

*CI: two-sided 95% score confidence interval

b. Asymptomatic screening study: To support screening individuals without symptoms or other reasons to suspect COVID-19, Mount Sinai performed another clinical study in which, 20 consecutively collected paired saliva and NP specimens from asymptomatic positive subjects and 100 consecutively collected paired saliva and NP specimens from asymptomatic negative subjects were tested. The paired NP swab specimens were tested using an FDA-authorized comparator according to the authorized Instructions For Use while the saliva specimens were tested with the Mount Sinai SARS-CoV-2 Assay using the QuantStudio 5 Real-time PCR instrument. The results of this study demonstrated 100% PPA and NPA between saliva and paired NP specimens (**Table 11**) and support the use of the Mount Sinai SARS-CoV-2 Assay for screening asymptomatic individuals.

Table 11: Summary of the Asymptomatic screening study

Mount Sinai SARS-CoV-2 Assay		**FDA-Authorized Comparator: Nasopharyngeal swabs**		
		Positive	**Negative**	**Total**
Saliva	**Positive**	**20**	**0**	**20**
	Negative	**0**	**100**	**100**
	Total	**20**	**100**	**120**
Positive Agreement		**100% (20/20); 95% CI* (83.9, 100)**		
Negative Agreement		**100% (100/100); 95% CI* (96.3, 100.0)**		

*CI: two-sided 95% score confidence interval

6) Usability Study:

Mount Sinai conducted a usability study to validate the use of Mount Sinai SARS-CoV-2 Collection Kit for collection of saliva specimens at home. The study included 30 participants (ranging from 5 to 53 years old), of which 8 collected samples at-home and 22 collected specimens in a simulated home environment. In both cases, the participants were provided with a usability questionnaire to capture their comprehension of the Instructions For Use and the user experience. Specimen collection by each participant was observed by a passive observer who also noted any difficulties encountered by the participants during sample collection.

Participants provided 100% favorable or neutral response to all the usability questions including questions regarding "ease of use of the home collection kit", "understanding the Instructions For Use" and "overall safety of the procedure". The observers did not note any significant deviations from the instructions in the way the participants collected specimens using the Mount Sinai SARS-CoV-2 Collection Kit. Only in three cases (one 6 years old and two 5 years old), the observers noted that the minors needed assistance from their parents for sample collection.

All the samples (30/30; 100%) received by the Mount Sinai lab met the sample accessioning criteria according to the Standard Operating Procedure (SOP). Overall, the results of the usability study demonstrated that the Mount Sinai SARS-CoV-2 Collection Kit is acceptable for use by the intended use population.

To align the Instructions For Use with those of other FDA-authorized saliva home collection kits with similar intended use, Mount Sinai made the following improvements to the IFU following completion of the Usability Study:

1. Warnings and Precaution statements were added.
2. Image of the kit contents was added.
3. Kit registration procedure was clarified.
4. Use of funnel was made mandatory.
5. Additional hand washing steps were added
6. Some instructional text was revised for clarity.
7. Sample drop-off instructions were updated.
8. Information regarding adult assistance for sample collection from minors was added.

LIMITATIONS:

1. The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

2. This Mount Sinai SARS-CoV-2 Assay is used for qualitative detection of SARS-CoV-2 RNA from human saliva specimen. The results cannot directly reflect the viral load in the original specimens.

3. Use of the Mount Sinai SARS-CoV-2 Assay in a general, asymptomatic screening population is intended to be used as part of an infection control plan, that may include additional preventative measures, such as a predefined serial testing plan or directed testing of high-risk individuals. Negative results should not be treated as definitive and do not preclude current or future infection obtained through community transmission or other exposures. Negative results must be considered in the context of an individual's recent exposures, history, and presence of clinical signs and symptoms consistent with COVID-19. Negative results for SARS-CoV-2 RNA from saliva should be confirmed by testing of an alternative specimen type if clinically indicated.

4. Asymptomatic individuals infected with COVID-19 may not shed enough virus to reach the limit of detection of the test, giving a false negative result. In the absence of symptoms, it is difficult to determine if asymptomatic individuals have been tested too late or too early. Therefore, negative results in asymptomatic individuals may include individuals who were tested too early and may become positive later, individuals who were tested too late and may have serological evidence of infection, or individuals who were never infected.

5. The specimens to be tested shall be collected, processed, stored and transported in accordance with the conditions specified in the instructions. Inappropriate specimen preparation and operation may lead to inaccurate results.

6. Extraction and amplification of nucleic acid from clinical samples must be performed according to the specified methods listed in this procedure. Other extraction approaches and processing systems have not been evaluated.

7. Amplification and detection of SARS-CoV-2 with the Mount Sinai SARS-CoV-2 Assay has only been validated with the instruments specified in the instructions. Use of other instrument systems may cause inaccurate results.

8. The limit of detection (LoD) is determined based on a 95% confidence of detection. When SARS-CoV-2 presents at or above the LoD concentration in the test specimen, there will be a low probability that SARS-CoV-2 is not detected. When SARS-CoV-2 presents below the LoD concentration in the test specimen, there will also be certain probability that SARS-CoV-2 can be detected.

9. Primers and probes for this kit target highly conserved regions within the genome of SARS-CoV-2. Mutations occurred in these highly conserved regions (although rare) may result in RNA being undetectable.

10. This kit uses an UNG/dUTP PCR products carryover prevention system which can prevent contamination caused by PCR products. However, in the actual operation process, the amplicon contamination can be avoided only by strictly following the instructions of PCR laboratories.

11. Negative results do not preclude SARS-CoV-2 infections and should not be used as the sole basis for treatment or other management decisions.

12. The impacts of vaccines, antiviral therapeutics, antibiotics, chemotherapeutics or immunosuppressant drugs on the Mount Sinai SARS-CoV-2 Assay have not been evaluated.

13. Use of this assay is limited to personnel who are trained in the procedure. Failure to follow these instructions may result in erroneous results.

WARNINGS AND PRECAUTIONS

- For In Vitro Diagnostic Use.
- For Emergency Use Authorization Only.
- For Rx Only.
- Do not use reagents past their expiration date
- For Use by individuals 18 years of age and older when self-collected
- For Use by individuals 14 years of age and older when self-collected under adult supervision
- For Use by individuals 5 years of age and older when collected with adult assistance
- This product has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA for use by the authorized laboratory.
- This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.